# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

## The effect of 12 weeks of combined exercise training on serum levels of nesfatin-1 in improving liver damage markers in men with non-alcoholic fatty liver disease.

## Protocol summary

**Study aim**
The effect of twelve weeks of combined training on liver enzymes in men with non-alcoholic fatty liver disease
**Design**
Experimental trial with exercise and control group, randomized on 20 patients
**Settings and conduct**
In the gym, doing a training program under the supervision of a trainer
**Participants/Inclusion and exclusion criteria**
The entry condition is to have grade 2 and 3 non-alcoholic fatty liver disease and not to consume alcohol and cigarettes
**Intervention groups**
The exercise intervention group, which evaluates the effect of exercise on fatty liver patients, and the control group, which does not do exercise
**Main outcome variables**
Liver enzyme levels

## General information

**Reason for update**
**Acronym**
**IRCT registration information**
IRCT registration number: **IRCT20240514061797N1**
Registration date: **2024-05-28, 1403/03/08**
Registration timing: **registered_while_recruiting**

Last update: **2024-05-28, 1403/03/08**
Update count: **0**
**Registration date**
2024-05-28, 1403/03/08

**Registrant information**
**Name**
hadi goudarzi
**Name of organization / entity**
**Country**
Iran (Islamic Republic of)
**Phone**
+98 66 4260 9702
**Email address**
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**Recruitment status**
**Recruitment complete**
**Funding source**

**Expected recruitment start date**
2024-05-21, 1403/03/01
**Expected recruitment end date**
2024-06-19, 1403/03/30
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
The effect of 12 weeks of combined exercise training on serum levels of nesfatin-1 in improving liver damage markers in men with non-alcoholic fatty liver disease.

**Public title**
Effect of exercise on fatty liver
**Purpose**
Health service research
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Having grade 2 and 3 fatty liver
**Exclusion criteria:**
Having heart disease, high blood pressure and chronic diseases Having a musculoskeletal problem
**Age**
From **30 years** old to **50 years** old

**Gender**
Male

**Phase**
N/A
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **20**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Using computer randomization methods. Using spss software, first we enter the people based on the number and select the select causes option in the data header section and then we enter the random option and the first option 50%, it tells us 10 people randomly.
**Blinding (investigator's opinion)**
Not blinded
**Blinding description**
**Placebo**
Not used
**Assignment**
Parallel
**Other design features**
Combined exercise protocol (resistance and high-intensity interval)

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics Committee Bu-Ali Sina University
**Street address**
Shahid Mustafa Ahmadi Roshan Chaharbagh, Boali Sina University
**City**
Hamedan
**Province**
Hamadan
**Postal code**
65178038695
**Approval date**
2024-03-04, 1402/12/14
**Ethics committee reference number**
IR.BASU.REC.1402.075

## Health conditions studied

### 1

**Description of health condition studied**
Non-alcoholic fatty liver
**ICD-10 code**
K76.0
**ICD-10 code description**
Fatty (change of) liver, not elsewhere classified

## Primary outcomes

### 1

**Description**
Ultrasound
**Timepoint**
At the beginning of the study and 12 weeks after sports training
**Method of measurement**
Ultrasound machine

### 2

**Description**
Liver enzymes
**Timepoint**
At the beginning of the study and twelve weeks after sports training
**Method of measurement**
Diagnostic kits of enzymes in the laboratory

### 3

**Description**
Lipid profile
**Timepoint**
At the beginning of the study and 12 weeks after sports training
**Method of measurement**
Biochemical kits in the laboratory

### 4

**Description**
blood sugar
**Timepoint**
At the beginning of the study and 12 weeks after sports training
**Method of measurement**
Blood sugar test kit

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
The first intervention group: sports exercises that include resistance training and high-intensity interval training during twelve weeks and three sessions per week are performed in a sports club.
**Category**
N/A

### 2

**Description**

Control group: The group that only ultrasound and blood tests are taken before and after twelve weeks without any intervention

**Category**

N/A

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Dr. Zarin Kob clinic

**Full name of responsible person**

Hadi Goudarzi

**Street address**

Paradise Square

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**Province**

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**Postal code**

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**Email**

hadigodarzi30@yahoo.com

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Bu-Ali Sina University

**Full name of responsible person**

Dr. Arash Ghorbani Chaghamarani

**Street address**

Shahid Mustafa Ahmadi Roshan Chaharbagh, Boali Sina University

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a.ghorbani@yahoo.com

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Bu-Ali Sina University

**Proportion provided by this source**

5

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

Academic

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Bu-Ali Sina University

**Full name of responsible person**

Hadi Goudarzi

**Position**

Student

**Latest degree**

Bachelor

**Other areas of specialty/work**

Physiology

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**
The names of the participants will not be disclosedکار

**Study Protocol**
Yes - There is a plan to make this available

**Statistical Analysis Plan**
Yes - There is a plan to make this available

**Informed Consent Form**
No - There is not a plan to make this available

**Clinical Study Report**
Yes - There is a plan to make this available

**Analytic Code**
No - There is not a plan to make this available

**Data Dictionary**
No - There is not a plan to make this available

**Title and more details about the data/document**
Only review results can be shared

**When the data will become available and for how long**
6 months after printing is completed

**To whom data/document is available**
It is accessible to everyone

**Under which criteria data/document could be used**
Research works

**From where data/document is obtainable**
Hadi Guderzi،09015413235

**What processes are involved for a request to access data/document**
The questions asked in the registration process are very unclear

**Comments**